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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,104	07/03/2001	Zvi Loewy	176650-155	1924
35509	7590	05/19/2004	EXAMINER	
DELSYS PHARMACEUTICAL CORPORATION 11 DEER PARK DRIVE SUITE 118 MONMOUTH JUNCTION, NJ 08852			BERKO, RETFORD O	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/898,104	Applicant(s) LOEWY ET AL.	
	Examiner Retford Berko	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/07/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement: *The Information Disclosure Statement filed January 22, 2002 and on July 3, 2001 are acknowledged.*

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Pletcher et al (US 6, 007, 630) and Debal et al (US 4, 072, 551).

Claim 1 is drawn toward a biochemical assay unit comprising integrated diagnostic form comprising a polymer substrate, an active ingredient (e.g. surfactant, carrier, binder, buffering agent, solvent and reagent) that is electrostatically deposited on the surface of the substrate. The unit further comprises of a porous layer having particles deposited on it; the particles have specific size wherein the layer retains the sample of liquid to be diagnosed. The dependent claims are drawn toward the active ingredient as being present in amount that does not vary from a target amount by more than 5% wt/%. The claims are also drawn toward the substrate as comprising a planar film, that the particles of the spreading layer comprise of latex beads having specific size (1-200 microns) or comprises of cellulose acetate. The claims are further drawn toward the particles being deposited in at least one layer, and the layer is uniform.

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3. Pletcher et al (Patent 630) discloses an invention in which plastic beads and powdered medicament (i.e. an active ingredient) are electrostatically deposited on a layer of polymeric substrate (abstract, col 5, lin 30, col 6, lin 5-20 and col 9, lin 20-25). Patent '630 discloses that the medicament is maintained on the substrate (col 11, lin 20), that the size of the beads is 50-200 microns (col 9, lin 25) and that specific quantities of the powdered medicament can be deposited onto the substrate (col 5, lin 30). Patent '630 does not disclose a planar film as substrate, does not disclose cellulose acetate or inorganic particulate material and does not disclose ingredients such as binders, buffering agent, solvent or reagent for detection.

4. Dabal et al (Patent '551) discloses an invention in which finely divided particles of active ingredients such as medicament of size 1-100 microns are electrostatically deposited on polymeric substrates as webs (col 4, lin 40, col 6, lin 1-5; col 16, lin 11-35; col 24, lin 35-40). Patent '551 discloses that the polymeric web substrate is made of film forming material (col 7, lin 15-30) and may contain both organic and inorganic solvents (col 8, lin 50-55). Patent '551 discloses that the active ingredients are deposited in a finely particulate powder form that is susceptible to analysis (col 16, lin 15-30). Patent '551 discloses that reflectance transmission spectrophotometry or other methods may be used to non-destructively analyze the deposited active ingredients on-line (abstract, col 12, lin 26, continuing to col 13, lin 1-25).

5. One of ordinary skill in the art would be motivated to make a structural unit comprising an integrated diagnostic form as disclosed in Patent '630 and Patent '551. One of ordinary skill in the art would be motivated make modifications such as modifying the size of the particles in the active ingredients deposited or including other materials and solvents in the ingredients used. One of ordinary skill would expect to obtain the same structural unit as obtained in the prior art

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references cited that would allow one of ordinary skill to perform analysis of the deposited ingredients on-line thereby obtaining an economical means of testing for the amounts of ingredients in the unit dosages during manufacture of medicaments. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill at the time the invention was made.

Double Patenting

1. Claim 1-11 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-11 of U.S. Patent No. 6, 287, 595. This is a provisional obviousness-type double patenting rejection.

The scope of Claims 1-11 teaches an invention comprising integrated diagnostic form comprising a polymer substrate, an active ingredient. The ingredient can be a drug or active substance or surfactant, carrier, binder, buffering agent, solvent and reagent. The active ingredient is electrostatically deposited on the surface of the substrate. The unit further comprises of a porous layer having particles deposited on it; the particles have specific size wherein the layer retains the sample of liquid to be diagnosed. The invention comprising the structural unit allows the ingredients to be analyzed. The scope of the invention in the prior art is the same as the scope of the instant claims 1-11. In fact, the instant claims are verbatim repetition of the claims in the prior art, providing objective evidence for obviousness double patenting.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date

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of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600